

### REMARKS

The present invention is directed to immunogenic compositions comprising fibroblast growth factor and/or vascular endothelial growth factor, to methods for treating cancer or hyperproliferative disorders in humans or animals, and also to methods for treating humans or animals in need of an immune response to a growth factor. Applicants appreciate the Examiner's careful review of the application and Response submitted on July 16, 2001 and submit the following comments in an effort to address the rejections raised in the September 25, 2001 Office Action..

Claims 5-13, 15-23 and 25-29 were pending prior to the issuance of the September 25, 2001 Office Action. In response to the Action and in order to facilitate prosecution, Claims 5, 6, 15 and 25 have been amended and Claim 16 has been cancelled without prejudice or disclaimer. Accordingly, following entry of this amendment, Claims 5-13, 15, 17-23 and 25-29 will be pending. No new matter has been added and support for the claims is found in the specification.

#### *Objection to the Specification*

In the September 25, 2001 Office Action, the Examiner stated that the amendment to the specification to correct the priority of the instant application was acknowledged but that now it no longer contained the same information as contained in the declaration which states that the instant application is a continuation of U.S.S.N. 09/265,213. Applicants have herein amended the specification to address the discrepancy. The instant application is now described as claiming priority to U.S.S.N. 09/265,213.

#### *Rejection of Claims*

##### *1. Rejection of Claims 5-13, 15-23 and 25-29 under 35 U.S.C. §112, second paragraph*

In the Office Action dated September 25, 2001, Claims 5-13, 15, 17-23 and 25-29 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as the invention.

In particular the Examiner stated that Claims 5, 15, and 25 are indefinite because "the heparin binding domain" and the "receptor binding domain" lack antecedent basis.

In order to facilitate prosecution, Applicants have herein amended Claims 5, 15, and 25 by deleting the word "the" before the phrase "heparin binding domain" and "receptor binding domain" and replacing it with the article "a". Reconsideration and withdrawal of the rejection are therefore respectfully requested.

*2. Rejection of Claim 6 under 37 C.F.R. 1.75(c)*

In the Office Action dated September 25, 2001, the Examiner rejected Claim 6 under 37 C.F.R. 1.75(c) for being of improper dependent form. Specifically, the Examiner noted that Claim 6 depends from Claim 5, but whereas Claim 5 uses closed language "consists of", Claim 6 uses open language, "comprises".

In order to facilitate prosecution, Applicants have herein amended Claim 6 replacing the word "comprises" with the phrase "consists of". Reconsideration and withdrawal of the rejection are therefore respectfully requested.

*3. Rejection of Claims 15-23 under 35 U.S.C. §112, first paragraph*

In the Office Action dated September 25, 2001, the Examiner rejected Claims 15-23 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention. Claim 15 remained rejected for reasons of record.

Dependent Claim 16 was newly rejected because according to the Examiner, the specification failed to teach immunogenic compositions comprising a peptide that comprises SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 or SEQ ID NO: 9, but instead teaches immunogenic compositions that comprise a peptide that consists of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 or SEQ ID NO: 9. In order to facilitate prosecution, Applicants have herein amended Claim 15 and cancelled Claim 16.

The Examiner also objected to the use of the phrase "receptor binding domain" in Claim 15 and dependent Claims 17-23. In order to advance prosecution, Applicants have herein amended Claim 15 by introducing language specifically identifying immunogenic fragments of the receptor binding domain of vascular endothelial growth factor as SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, or SEQ ID NO: 9.

In light of the above described amendments and remarks, Applicants respectfully request reconsideration and withdrawal of this rejection.

*4. Rejection of Claim 6 under 35 U.S.C. §102(b)*

In the September 25, 2001 Office Action, Claim 6 was rejected under 35 U.S.C. §102(b) as being anticipated by EP281822 (European Patent Application, Takeda Chemical Industries, Ltd. Senoo, M. et al. (1988)). Claim 6 remained rejected for reasons of record. In the March 14, 2001 Office Action, the Examiner had rejected Claim 6 stating that EP281822 teaches the invention as described in Claim 6 because it teaches immunization of mice with an FGF mutein combined with Freund's complete adjuvant which results in the production of monoclonal antibodies. The Examiner stated in the September 25, 2001 Office Action that Claim 6 is drawn to compositions comprising a peptide that comprises SEQ ID NO:1 or SEQ ID NO:2. According to the Examiner, Senoo et al. teach immunogenic peptides that comprise the amino acid sequences of SEQ ID NO:1 or SEQ ID NO:2. Applicants respectfully traverse.

Applicants' novel discovery comprises the finding of a previously unidentified genus of peptides from heparin binding domain regions of fibroblast growth factor (FGF) that are immunogenic. The compositions recited in the claims of the present invention are characterized according to structure (location in the heparin binding domain of FGF) and function (immunogenicity). Senoo et al. fail to identify any such peptides. Senoo et al. are concerned primarily with the cloning and expression of FGF muteins for the purpose of stimulating angiogenic activity. In order for claims to be rejected under 35 U.S.C. §102(b) each and every element of the claim must be disclosed by the cited reference. Applicants respectfully submit that Senoo et al. fail to identify a genus of immunogenic peptides located in the heparin binding domain of FGF and therefore Senoo et al. fail to anticipate Claim 6.

In light of the above discussion, Applicants respectfully request reconsideration and withdrawal of this rejection.

*5. Rejection of Claims 5 and 6 under 35 U.S.C. §102(b)*

In the September 25, 2001 Office Action, the Examiner rejected Claims 5 and 6 under 35 U.S.C. §102(b) as being anticipated by Ungheri et al. (United States Patent No. 5,288,704). The Examiner stated that because the instant application is a continuation-in-part application of the parent application, which does not appear to have contemplated immunogenic fragments that consist of the heparin binding domain of FGF, and fails to disclose SEQ ID NO:1 or SEQ ID NO:2, the effective filing date of the instant application is considered to be the filing date with which to compare the claims with the prior art. Applicants respectfully traverse.

With regard to the priority date, Applicants respectfully submit that Applicants parent application sets forth in great detail methods for identifying immunogenic peptides from growth factors such as FGF. The present invention provides further information in identifying heparin binding domain regions of FGF as a location for immunogenic peptides. Therefore, the parent application provides a general teaching for identifying immunogenic peptides, and the present application provides specific examples.

Applicants respectfully submit that Ungheri et al. fail to anticipate Claims 5 and 6 because as stated above, in order for claims to be rejected under 35 U.S.C. §102(b) each and every element of the claim must be disclosed by the cited reference. Applicants respectfully submit that Ungheri et al. fail to identify immunogenic peptides located in the heparin binding domain of FGF and therefore Ungheri et al. fail to anticipate Claims 5 and 6.

In light of the above discussion, Applicants respectfully request reconsideration and withdrawal of this rejection.

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6. *Rejection of Claims 6 and 15-23 under the Judicially Created Doctrine of Obviousness-Type Double Patenting*

In the September 25, 2001 Office Action, the Examiner rejected Claims 6 and 15-23 under the judicially created doctrine of obviousness-type double patenting stating that although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 6 is broadly drawn to compositions comprising SEQ ID NO: 1 or SEQ ID NO:2, and because Claims 15-23 are broadly drawn to compositions comprising SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 or SEQ ID NO: 9. As discussed above, Claim 6 has been amended and now recites compositions consisting of SEQ ID NO: 1 or SEQ ID NO:2, and Claims 15 has been amended and now recites compositions consisting of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 or SEQ ID NO: 9.

In light of the claim amendments, the rejection of Claims 6 and 15-23 under the judicially created doctrine of obviousness-type double patenting is considered moot. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

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*Conclusion*

In light of the amendments Applicants are of the opinion that Claims 5-13, 15, 17-23 and 25-29 are now in condition for allowance. Such action is respectfully requested. If the Examiner believes any informalities remain in the application which may be corrected by Examiner's Amendment, or there are any other issues which can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 745-2463 is respectfully solicited.

Respectfully submitted,

  
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